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10/749,538

12/30/2003

Akito Nakamura

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

MAIL DATE

DELIVERY MODE

02/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/749,538 | Applicant(s) NAKAMURA ET AL. | |
| | Examiner MISOOK YU | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007 and 20 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/29/07, 07/13/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1-21 are pending and under consideration.

Claim Rejections - 35 USC § 112

The rejection of claims 1-5 and 7-12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for combination of a reshaped human PM-1 antibody and melphalan, does not reasonably provide enablement for any other combination. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

First part of the enablement rejection is withdrawn in view of the applicant's remark at page 8 regarding availability of the antibody, and the deposit statement in the specification.

The second part of the rejection has to do with the specification does not teach one of skill to practice the full scope without resorting to an undue experimentation, i.e. combination of a genus of nitrogen mustard anticancer agents and the genus of IL-6R

antibodies is not enabled. The specification discloses only the combination of melphalan and the reshaped human PM-1 antibody has synergistic effect.

Applicant argues the specification teaches the skilled artisan how to make and use the claimed genus of antibodies that inhibit signal transmission of IL-6 by blocking the binding of IL-6 ligand to IL-6 receptor to treat myeloma synergistically with a nitrogen mustard anticancer agent and making and using genus of IL-6 antibodies and genus of nitrogen mustard agents are described in the specification.

Applicant's arguments have been fully considered but found unpersuasive because claims recite "synergistic therapeutic effect". Applicant argued that the claims 1 and 2 in 09/202,802 (now U.S. Patent No. 6,692,742) is not obvious over Suzuki et al (1992, European Journal of Immunology, vol. 28, pages 1989-93) in view of either Sarosy et al (1988, J. Clinical Oncology , vol. 6, pages 1768-82) , Evans et al (Cancer Chemotherapy and Pharmacology, vol. 8, pages 175-8, Abstract), or US Patent 5,882,941 (1994) because synergy is an unexpected result and cannot be predicted without an actual experimentation. In addition, as Dancey et al of record at the paragraph bridging pages 649-50 teach combination of anticancer drugs "can be considered to be synergistic that is, to provide greater benefit in combination than evidence by the additive effects of their individual activity and no regimen is selected on the basis of foreknowledge of sensitivity of an individual patient's tumor to the drugs. This empirical approach has been justified by the lack of means of identifying which tumors might be sensitive to individual agents or to a combination of agents". This teaching indicates synergistic effect can be determined by experiments only; the art of

finding synergy between two anti-cancer drugs are unpredictable. Considering the unpredictable state of art, limited guidance, limited examples in the specification how to use the instantly claimed invention, broad breath of the claims, it is concluded that undue experimentation is required to practice the full scope of invention.

Double Patenting

The terminal disclaimer filed on 03/14/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,692,742 has been reviewed and is accepted. The terminal disclaimer has been recorded.

However, claims 1-12 **are provisionally rejected** under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 and 7-9 of copending Application No. 10/098,874. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented because the required terminal disclaimer has not been filed yet. Applicant remarks about holding this issue in abeyance is noted.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU
Primary Examiner
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/MISOOK YU/
Primary Examiner, Art Unit 1642